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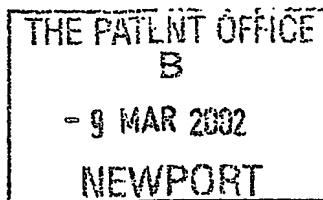
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P01/7700 0.00-0205572.1

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1. Your reference 50/433/P/GB

2. Patent number 0205572.1

9 MAR 2002

3. Full name, address and postcode of the or of each applicant (underline all surnames)
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NG2 7BZ

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

England

4. Title of the invention

Medicament Delivery and Packaging

5. Name of your agent (if you have one)

Adamson Jones

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

Broadway Business Centre
32a Stoney Street
Nottingham
NG1 1LL

Patents ADP number (if you know it)

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Country

Priority application number
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Date of filing
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7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

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8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if

No

- a) any applicant named in part 3 is not an inventor, or
 - b) there is an inventor who is not named as an applicant, or
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Description 7

Claim(s)

Abstract

Drawing(s) 3 *23*

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Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (*Patents Form 7/77*)

Request for preliminary examination and search (*Patents Form 9/77*)

Request for substantive examination (*Patents Form 10/77*)

Any other documents
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11.

I/We request the grant of a patent on the basis of this application.

Signature

Date

[Signature] 8 March 2002

12. Name and daytime telephone number of person to contact in the United Kingdom

Dr S A Jones

0115 9247 147

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Medicament Delivery and Packaging

This invention relates to delivery devices and packaging for medicaments, in particular to delivery devices and packaging for the administration of medicaments by inhalation.

The most common methods of administering powdered medicament by inhalation are pressurised aerosol inhalers and dry powder inhalers. Conventional dry powder inhalers use medicament packaged in a gelatine capsule. An improved method of administration, however, is disclosed in WO 98/26828.

WO 98/26828 discloses several delivery devices for use with medicament containers that contain pre-formed openings through which medicament is dispensed within the delivery device. The delivery devices all comprise a mouthpiece, air inlet means and a chamber in which the medicament container is located. In use, air is drawn into the chamber causing the medicament container to follow an orbital path around the chamber. In this way the medicament is dispensed through the openings of the medicament container and medicament entrained with air is drawn out of the chamber and through the mouthpiece. The disclosed delivery devices include single-use delivery devices pre-loaded with a medicament container and multi-use delivery devices in which a medicament container is inserted into the chamber before use.

The delivery devices and medicament packages disclosed in WO 98/26828 represent a considerable advance over the prior art, but are nonetheless susceptible to further improvement. In particular, the movement of the medicament container may, in use, be audible, which may be undesirable in certain situations.

There has now been devised an improved form of medicament delivery device and medicament packaging that overcomes or substantially mitigates the above-mentioned and/or other disadvantages of the prior art. In particular, it has surprisingly been found that a medicament container of the general type disclosed

in WO 98/26828 may be caused to empty satisfactorily without undergoing movement.

5 According to the invention, there is provided a system for the administration of a powdered medicament by inhalation, the system comprising a container containing a unit dose of medicament in powder form, the container having at least one dispensing aperture, and a device having a chamber adapted to receive said container, the device further comprising air inlet means by which air may be drawn into the chamber and mouthpiece means by which air and entrained medicament
10 may be drawn out of the chamber, wherein the container, in use, is stationary within the chamber.

The system according to the invention is advantageous primarily in that the medicament container empties without undergoing movement. As a result, the
15 noise generated in use is low. Because the container does need to undergo motion brought about by the airflow in the device, the required airflow in the device is relatively low, leading to greater ease of use, eg by users with impaired lung function.

20 The device may be configured for single or repeated use. In either case means are provided for storing the container whilst sealing the at least one aperture, introducing the container into the chamber and holding the container stationary within the chamber. Preferably, said means take the form of an enclosure of deformable material attached to a part of the container by attachment means and
25 arranged such that manual pressure introduces the container to the chamber. Said attachment means is preferably a stud with an enlarged upper portion, preferably integrally formed on the container, projecting through an aperture in the enclosure.

30 According to another aspect of the invention, there is provided a system for the administration of a powdered medicament by inhalation, the system comprising a container containing a unit dose of medicament in powder form, the container having at least one dispensing aperture, and a device having a chamber adapted

to receive said container, the device further comprising air inlet means by which air may be drawn into the chamber and mouthpiece means by which air and entrained medicament may be drawn out of the chamber, wherein a part of the wall of the chamber is formed as a deformable enclosure within which the container is received such that the at least one dispensing aperture is sealed and from which the container can be introduced into the chamber by pressure applied to the external surface of the deformable enclosure, the container being connected to the enclosure such that when introduced into the chamber the container is held stationary.

In the case of a repeated use device, the enclosure and container may form a medicament package which may be removed from the delivery device. In such a case the medicament package is attached to the device preferably by means of a rigid support which is bonded to the enclosure and receiving means such as a groove formed in the device such that the rigid support can be engaged with the groove.

The chamber is preferably circular in form. The air inlet means are preferably arranged such that air enters the chamber substantially tangentially so as to facilitate the emptying of the container. There are preferably provided a plurality of air inlets, most preferably opening into the chamber at substantially equiangularly spaced positions.

The medicament container may have any shape. However, the container is preferably cylindrical or substantially cylindrical. The diameter of the cylinder is generally greater than its depth.

The medicament container is preferably provided with a plurality of dispensing apertures. In the case of a cylindrical container, the dispensing apertures are preferably disposed equiangularly around the cylindrical periphery of the container.

The device may be manufactured from materials conventionally utilised in inhalation drug delivery devices. Examples include plastics materials such as polycarbonate,

polypropylene and polyethylene and metals such as aluminium and stainless steel. The medicament container and enclosure are preferably of a material which is substantially impermeable to moisture. The enclosure is preferably of elastomeric material, most preferably a medical grade thermoplastic rubber. The medicament container is preferably of plastics material, most preferably polypropylene.

The invention will now be described in greater detail, by way of illustration only, with reference to the accompanying drawings, in which

10 Figure 1 is a plan view of a first embodiment of a powdered medicament inhaler according to the invention;

Figure 2 is a side view of a medicament container that forms part of the inhaler of Figure 1;

15

Figure 3 is a sectional view on the line III-III in Figure 1, of the inhaler;

Figure 4 is a sectional view on the line IV-IV in Figure 3;

20 Figure 5 is a sectional view on the line III-III in Figure 1, of the inhaler in use;

Figure 6 is a plan view of a second embodiment of a powdered medicament inhaler according to the invention;

25 Figure 7 is a sectional view on the line VII-VII in Figure 6;

Figure 8 is a side view of a medicament package according to the invention;

30 Figure 9 is a view similar to that of Figure 7, of the inhaler engaged with a medicament package; and

Figure 10 is a view similar to that of Figure 9, of the inhaler in use.

Referring first to Figures 1 and 2, a first embodiment of a medicament inhaler according to the invention is generally designated 10. The inhaler comprises a main body 18, an enclosure 14 and a medicament container 20. The main body 18 and the medicament container 20 are both moulded in plastics material, whilst the enclosure 14 is of elastomeric material.

Referring to Figure 2, the container 20 has a cylindrical lower section and an upper section of generally domed or conical shape. The cylindrical lower section of the container 20 contains a series of equiangularly spaced circular apertures 21. At the apex of the upper section, the container 20 is formed with an integral stud 22 having an enlarged upper portion.

Referring to Figures 1, 3 and 4, the main body 18 comprises a mouthpiece 11, a passageway 16, a chamber 19, conduits 12a, 13a and air inlets 12, 13. The mouthpiece is a generally elliptical opening in one end of the main body 18. The passageway extends from the mouthpiece 11 and through the lower part of the main body 18. The chamber 19 is cylindrical in shape and is positioned above the passageway 16. The chamber 19 communicates with the passageway 16 by means of a series of openings which make up a generally circular grid 15 in the centre of the base of the chamber 19, as shown in Figure 4.

There are two front air inlets 12 and two rear air inlets 13 which connect the wall of the chamber 19 and the exterior of the inhaler 10 by means of respective conduits 12a, 13a, as shown in Figure 4. The conduits 12a, 13a are aligned substantially tangentially to the wall of the chamber 19 and connect to the chamber 19 at equiangularly spaced locations.

Referring now to Figure 3, the upper wall of the chamber 19 includes a circular aperture 17. The interior wall of the circular aperture 17 is bonded to the enclosure 14, the enclosure 14 extending above the chamber 19. The enclosure 14 is of similar shape to the container 20 save that the enclosure 14 has an open lower end and a circular aperture at its apex. The enclosure 14 is dimensioned such that the container 20 is closely received within the enclosure 14 with an

interference fit and the stud 22 is pressed through the aperture of the enclosure 14, thereby holding the container 20 within the enclosure 14. The aperture of the enclosure 14 is dimensioned such that the lower portion of the stud fits closely within the aperture of the enclosure 14. The inhaler 10 is shown in Figure 3 prior to use, with the medicament sealed within the container 10.

When the patient is ready to use the inhaler 10, the patient applies downward finger pressure on the enclosure 14 such that the enclosure 14 is turned inside out and extends partially into the chamber 19. The stud 22 projecting through the aperture of the enclosure 14 remains in this position thereby holding the container 20 in the centre of the chamber 19, as shown in Figure 5.

The patient then places the mouthpiece 11 to their mouth and inhales. Air is drawn through the air inlets 12,13, along the conduits 12a,13a and substantially tangentially into the chamber 19. The airstream passes through the grid 15 and along the passageway 16 to the patients mouth. The stream of air entering the chamber 19 causes the medicament to be dispensed from within the medicament container 20, through the apertures 21 of the container 20, into the chamber 19. The medicament is entrained in the airstream which passes out of the chamber 19 through the grid and is inhaled by the patient. The first embodiment 10 is a single-use delivery device and would be discarded after use.

Turning now to Figures 6, 7, 8 and 9, a second embodiment of a medicament inhaler according to the invention is generally designated 50. The second embodiment 50 is similar to the first embodiment 10 save that the medicament container 61 and the enclosure 62 together form a separate component from the inhaler 50.

The enclosure 62 and the medicament container 61, for use with the second embodiment of the inhaler 50, are identical to the enclosure 14 and container 20 of the first embodiment of inhaler 10. The enclosure 62 and container 61, together with a support ring 63, form a medicament package 60, as shown in Figure 8. The container 61 is closely received with an interference fit, as in the first embodiment,

within the enclosure 62, with the stud 65 of the container 61 projecting out of the aperture of the enclosure 62. The support ring 63 comprises an annular plate and a vertically orientated upper and lower skirt on the inner edge of the annular plate. The support ring 63 fits closely around, and is bonded to, the outside of the
5 cylindrical lower section of the enclosure 62.

The inhaler 50 is similar to the main body 18 of the first embodiment 10, save that the enclosure 62 is not bonded to the circular aperture 52 in the upper end of the chamber 56. The aperture 52 contains a groove 53 and an upper section of
10 enlarged diameter, such that the support ring 63 of the medicament package 60 may be snap fitted from above into the groove 53 within the aperture 52. The upper surface of the inhaler 50 is provided with a rectangular depression 51 which extends from the aperture 52 and is dimensioned to accommodate the pad of the patient's thumb.

15

In order to load the inhaler 50, the medicament package 60 is snap fitted, as described above, into the aperture 52, as shown in Figure 10. The method of use is thenceforth identical to the method of use for the first embodiment 10. After use, however, the patient places their thumb in the depression 51 and exerts an
20 upward pressure on the support ring 63 of the medicament package 60, thereby removing the medicament package from the aperture 52. The inhaler 50 may subsequently be reloaded with another medicament package 60.

Fig 3

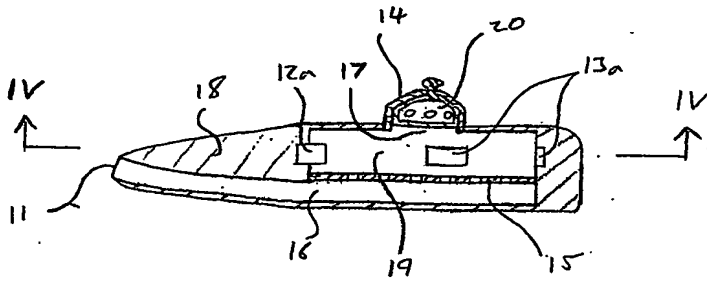


Fig 5

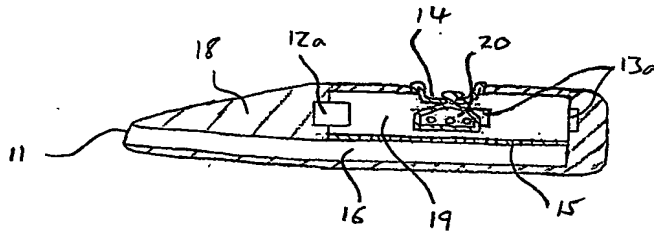


Fig 1

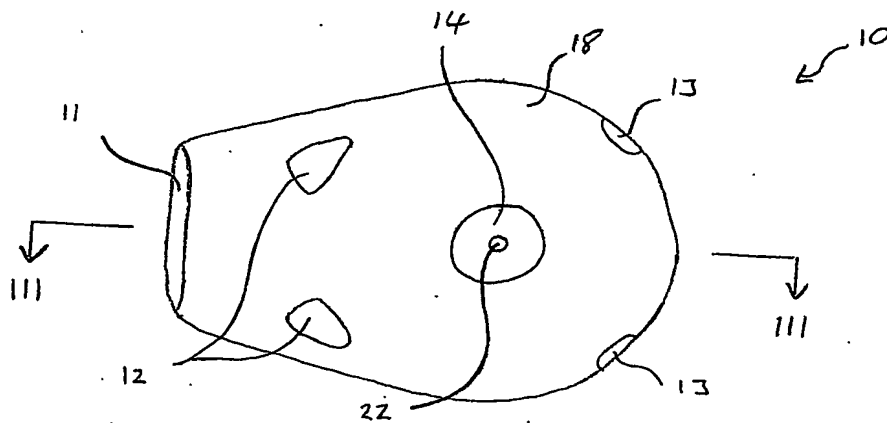


Fig 2

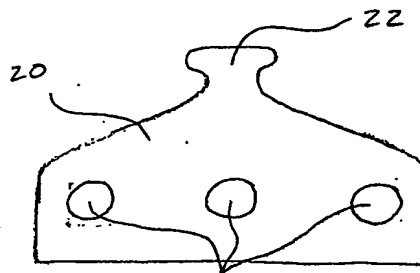


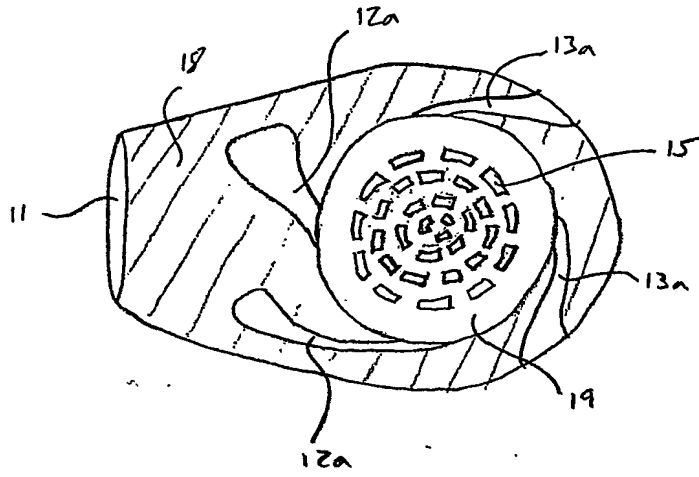
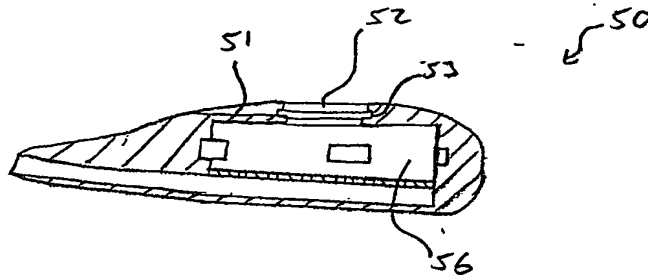
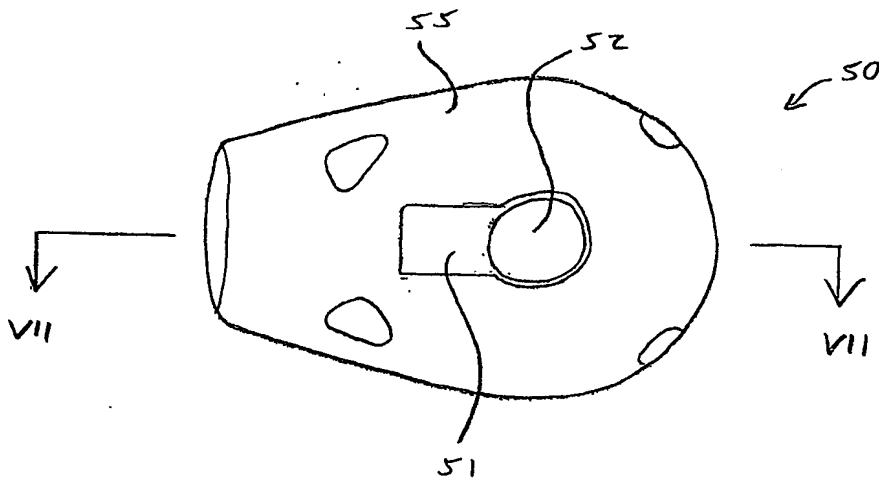
Fig 4Fig 7Fig 6

Fig 8

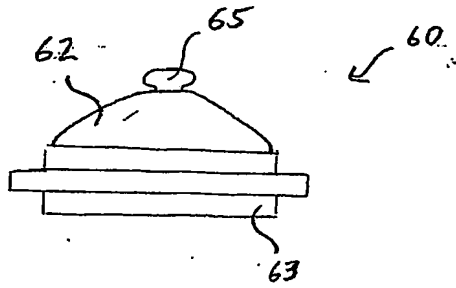


Fig 9,

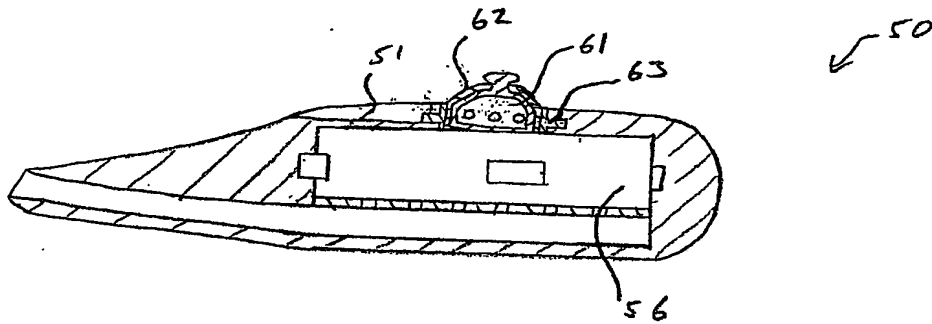
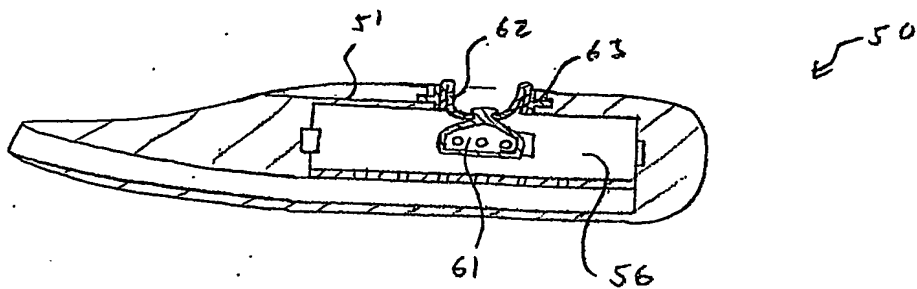


Fig 10



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